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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,118	12/30/2003	Richard L. Boyd	NOR-012CP2 and 286336.151	3277

23483 7590 05/08/2006

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EXAMINER	
NGUYEN, QUANG	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,118	BOYD, RICHARD L.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-34,36-43,45-51,53-59,61-68,70-78,80-82,84-86 and 90-101* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 29-34,36-43,45-51,53-59,61-68,70-78,80-82,84-86 and 90-101.

DETAILED ACTION

Claims 29-34, 36-43, 45-51, 53-59, 61-68, 70-78, 80-82, 84-86 and 90-101 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction

I. Claims 29-43, 45-51, 80-82, 90 and 92-101, drawn to a method for treating or preventing autoimmune disease in a patient comprising the steps of depleting T cells in the patients; and reactivating the thymus of the patient, classified in class 514, subclasses 2, 800; class 424, subclasses 93.1, 85.2, for examples.

II. Claims 53-59, 61-68, 70-78, 84-86, 90, 93-94 and 101, drawn to a method for treating an allergy in a patient comprising the steps of ablating T cells in the patients; and reactivating the thymus of the patient, classified in class 514, subclasses 2, 800; class 424, subclasses 93.1, 85.2, for examples.

III. Claim 91, drawn to a method for increasing virus-specific peripheral T cell responsiveness of a patient with an at least partially atrophied thymus comprising the step recited in claim 91, classified at least in class 424, subclass 93.1, for example.

The inventions are distinct because of the following reasons:

The methods of Groups I-III are drawn to distinct methods having different starting materials, different method steps and different desired end-results, and therefore they would require different technical considerations for achieving these different desired end-results. For example, Group I is drawn specifically to a method for treating or preventing autoimmune disease in a patient; Group II is directed specifically to a method for treating or preventing an allergy in a patient; and Group III is drawn specifically to a method for increasing virus-specific peripheral T cell responsiveness of a patient with at least partially atrophied thymus containing the step of exposing the patient to a virus, which is not required in any of the methods of Groups I-II. An autoimmune disease has different causes and symptoms from those of an allergy, and therefore their respective treatment or prophylactic methods require different technical considerations for attaining the desired outcomes. It is further noted that claim 90 is included in both Groups I-II because the search and examination of this claim would not be undue burden for the examiner in the search and examination of either Group I or Group II.

Searching and examining the inventions of Groups I-III would impose a serious burden since a search for a method of treating autoimmune disease in a patient of Group I would not necessarily reveal a method of treating an allergy of Group II and/or a method for increasing virus-specific peripheral T cell responsiveness of a patient with at least partially atrophied thymus of Group IIII. It would be unduly burdensome for the examiner to perform a complete search of the defined areas in both the patent and non-patent literature, and/or consider the patentability of all the inventions in a single

application, particularly in light of the number of claims and their numerous limitations. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction

A. Should Applicants elect the invention of Group I, this application contains claims directed to the following patentably distinct species of disruption of sex-steroid-mediated signaling to the thymus to reactivate the thymus of the claimed invention:

1. surgical castration and 2. chemical castration or administration of a pharmaceutical.

The species are independent or distinct because a surgical castration and a chemical castration are two distinct processes utilizing different techniques and materials.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 29, 90, 99-100 are generic.

Additionally, should Applicants elect the species 2 above, this application contains claims directed to the following patentably distinct species of a pharmaceutical of the claimed invention:

a. LHRH agonists; b. LHRH antagonists; c. anti-LHRH vaccines; d. anti-androgens; e. anti-estrogens; f. SERMs; g. SARMs; h. SPRMs; i. ERDs; j. aromatase inhibitors; k. anti-progestogens; l. Dioxalan derivatives; or m. a specific combination of species a-l.

The species are independent or distinct because each pharmaceutical is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 29, 31, 47-49, 90 and 99-100 are generic.

(i) Additionally, should Applicants elect the a species containing LHRH agonists, this application contains claims directed to the following patentably distinct species of LHRH agonists of the claimed invention:

A specific named LHRH agonist or a specific combination of LHRH agonists recited in the Markush group of claim 50.

The species are independent or distinct because each recited LHRH agonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 29, 31, 47-50, 90 and 99-100 are generic.

(ii) Additionally, should Applicants elect the a species containing LHRH antagonists, this application contains claims directed to the following patentably distinct species of LHRH antagonists of the claimed invention:

A specific named LHRH antagonist or a specific combination of LHRH antagonists recited in the Markush group of claim 51.

The species are independent or distinct because each recited LHRH antagonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 29, 31, 47-49, 51, 90 and 99-100 are generic.

This application contains claims directed to the following patentably distinct species of administered cells to the patient of the claimed invention:

i. stem cells; ii. progenitor cells; iii. dendritic cells; or iv. a specific combination of species i-iii.

The species are independent or distinct because each recited cell type is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 29, 31-32 and 41 are generic.

This application contains claims directed to the following patentably distinct cytokine species:

A specific named cytokine species or a specific combination therefore recited in the Markush group of claim 81.

The species are independent or distinct because each recited cytokine is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 29 and 80-81 are generic.

This application contains claims directed to the following patentably distinct growth factor species:

A specific named growth factor species or a specific combination therefore recited in the Markush group of claim 82.

The species are independent or distinct because each recited growth factor is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 29, 80 and 82 are generic.

B. Should Applicants elect the invention of Group II, this application contains claims directed to the following patentably distinct species of disruption of sex-steroid-mediated signaling to the thymus to reactivate the thymus of the claimed invention:

1. surgical castration and 2. chemical castration or administration of a pharmaceutical.

The species are independent or distinct because a surgical castration and a chemical castration are two distinct processes utilizing different techniques and materials.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 53 and 90 are generic.

Additionally, should Applicants elect the species 2 above, this application contains claims directed to the following patentably distinct species of a pharmaceutical of the claimed invention:

a. LHRH agonists; b. LHRH antagonists; c. anti-LHRH vaccines; d. anti-androgens; e. anti-estrogens; f. SERMs; g. SARMs; h. SPRMs; i. ERDs; j. aromatase inhibitors; k. anti-progestogens; l. Dioxalan derivatives; or m. a specific combination of species a-l.

The species are independent or distinct because each pharmaceutical is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 55 and 74-76 are generic.

(i) Additionally, should Applicants elect the a species containing LHRH agonists, this application contains claims directed to the following patentably distinct species of LHRH agonists of the claimed invention:

A specific named LHRH agonist or a specific combination of LHRH agonists recited in the Markush group of claim 77.

The species are independent or distinct because each recited LHRH agonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 55 and 74-77 are generic.

(ii) Additionally, should Applicants elect the a species containing LHRH antagonists, this application contains claims directed to the following patentably distinct species of LHRH antagonists of the claimed invention:

A specific named LHRH antagonist or a specific combination of LHRH antagonists recited in the Markush group of claim 78.

The species are independent or distinct because each recited LHRH antagonist is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 55, 74-76 and 78 are generic.

This application contains claims directed to the following patentably distinct species of administered cells to the patient of the claimed invention:

i. stem cells; ii. progenitor cells; iii. dendritic cells; or iv. a specific combination of species i-iii.

The species are independent or distinct because each recited cell type is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 53, 55, 57 and 66 are generic.

This application contains claims directed to the following patentably distinct cytokine species:

A specific named cytokine species or a specific combination therefore recited in the Markush group of claim 85.

The species are independent or distinct because each recited cytokine is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 53 and 84-85 are generic.

This application contains claims directed to the following patentably distinct growth factor species:

A specific named growth factor species or a specific combination therefore recited in the Markush group of claim 86.

The species are independent or distinct because each recited growth factor is structurally and biochemically distinct one from the others.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 53, 84 and 86 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's SPE, Dave Nguyen, may be reached at (571) 272-0731.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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QUANG NGUYEN, PH.D
PATENT EXAMINER